

10.4 ± 10.6%, respectively. Procedural success was 99%. Coronary dissections occurred in 14.7%, and bailout BMS was required in 13 patients (11.9%). Mean follow-up was 7.5 months; follow-up rate was 99%. Cumulative MACE at follow-up was 8.7%, with 1% all-cause death, 1% myocardial infarction, 6.9% overall target vessel revascularization; of which 2.9% were target lesion revascularizations, and no vessel thrombosis. Angiographic follow-up of a subset of patients (n=26) demonstrated late luminal loss of 0.30 ± 0.36 mm and 0.33 ± 0.37 mm for the in-DCB and in-segment analyses, respectively.

Conclusions: The Valentines II trial demonstrated the safety and efficacy of second-generation DIOR DCB as adjunct to POBA in an all-comer population with de novo coronary lesions. This approach achieved high procedural success with acceptable rates of bailout stenting and low MACE rates at mid-term follow-up, and offers an attractive alternative for revascularization of patients who are not good candidates.

TCT-588

Cost-effectiveness of paclitaxel-coated balloon angioplasty for treatment of coronary stenosis in bare-metal stents

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Background: In-stent restenosis (ISR) is a persistent problem limiting the long-term success of percutaneous coronary intervention. Recent studies have demonstrated safety and efficacy of drug-eluting balloon (DEB) angioplasty for the treatment of coronary ISR. The cost-effectiveness of this practice is unknown.

Methods: A Markov state-transition decision analytic model was used to assess the comparative cost-effectiveness of two common treatment strategies for bare-metal stent (BMS)-ISR: stenting with paclitaxel-eluting DES (drug-eluting stent) versus paclitaxel-eluting balloon angioplasty (SeQuent Please). The model accounted for varying procedural efficacy rates, complication rates, and cost estimates. Data on procedural outcomes associated with both treatment strategies were derived from the literature, and the cost analysis was conducted from a German health care payer perspective. Effectiveness was expressed as life-years gained. Cost-effectiveness was calculated by dividing the difference in mean costs by the difference in effectiveness.

Results: In the base-case analysis, initial procedure costs amounted to \$4,497.27 for DEB angioplasty and to \$4,128.81 for DES implantation. Over a 12-month time horizon, the DEB strategy was found to be less costly (\$5,154.47 versus \$6,619.98) and slightly more effective in terms of life expectancy (0.983 versus 0.976 years) than the DES strategy. Extensive sensitivity analyses indicated that, in comparison with DES implantation, the cost advantage of the DEB strategy was robust to clinically plausible variations in the values of key model input parameters. The variables with the greatest impact on base case Results were the duration of dual antiplatelet therapy after DEB angioplasty, the use of generic clopidogrel, and variations in the costs associated with the DEB device.

Conclusions: DEB angioplasty is a cost-effective treatment option for coronary BMS-ISR. The higher initial costs of DEB are more than offset by later cost savings, predominantly as a result of reduced medication costs. DEB angioplasty can be regarded as one of the rare innovative medical interventions that are cost-saving at equal or even increased effectiveness.

TCT-589

Reaching Further in the Treatment of Calcified Small Vessel Disease - is Rota-DEB an Option?

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Background: In spite of all the technical developments that have taken place in coronary artery disease treatment, small diffusely calcified vessels are yet challenging. Rotational atherectomy (ROTA) has an undisputed role in the debulking of severely calcified arteries, followed by drug eluting stent implantation for best long term Results. There are cases, however, where delivering a stent proves to be impossible or inappropriate. In such patients (pts) drug eluting balloons (DEB) could provide a therapeutic option. AIMS: We present the preliminary Results of the experience of 3 cardiovascular intervention centers on the use of ROTA followed by DEB (ROTA-DEB).

Methods: All data on pts submitted to rotablation is prospectively collected in a database. Pts in which ROTA-DEB was performed, accepted to angiographic follow-up (Fup-angio) after a minimum of 6 months. Lesions were assessed by QCA at the time of intervention. Post ROTA-DEB and at Fup, QCA was done after intra coronary administration of nitrates in the same plane as basal QCA and along the length of the DEB.

Results: In our multicenter registry, from 1/6/2009 to 31/5/2012, 204 consecutive pts were submitted to ROTA, of which 21 (10.3%) were followed by DEB (32 balloons (average size: 2.45 (2-4) mm x 21.66 (15-30) mm). Most common indications for DEB were: distal vessel ≤ 2 mm (59.4%) and difficulties in stent delivering (25%). Angio-

graphic success was achieved in all but 2 lesions (91%); 1 final QCA > 50% and 1 required bail-out stenting. All pts showed a marked improvement in clinical status. At 12 months, freedom from major cardiac adverse events was 90%. Fup-angio (refused by 3 pts) was obtained at a median of 424 ± 254 days. QCA analysis showed an average late luminal loss (LLL) of -6% (-62% to +75%). LLL > 50% was present in 1 pt.

Conclusions: Although these are still small numbers, Results seem very promising, considering the complexity of the lesions. For very severe, diffusely calcified coronary artery disease, ROTA-DEB constitutes a good therapeutic option when a stent cannot be implanted.

TCT-590

Efficacy of Paclitaxel-eluting Balloon Catheter in Patients with Recurrences after Drug-eluting Stent Implantation for In-stent Restenosis

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Background: The efficacy of paclitaxel-eluting balloon (PEB) for in-stent restenotic lesions is proven; however, its efficacy for recurrences after drug-eluting stent (DES) implantation for in-stent restenosis (stent in stent lesions) remains unclear. The aim of this study was to investigate the efficacy of PEB in patients with recurrences after DES implantation for in-stent restenosis.

Methods: From November 2004 to December 2011, 159 consecutive lesions who underwent revascularization for recurrences after DESs for in-stent restenosis were enrolled in this study [77 treated with PEB and 82 treated with conventional balloon angioplasty (BA)]. Follow-up angiogram was obtained 6 months after the procedure. We compared characteristics of patients and lesions between the two groups (PEB group vs BA group).

Results: No significant differences were observed in clinical characteristics between the two groups. Angiographic characteristics before the procedure were similar between the two groups (Reference diameter: 3.07 ± 0.56 mm vs 3.07 ± 0.55 mm, p = 0.9; Lesion length: 18.0 ± 15.0 mm vs 15.0 ± 11.7 mm, p = 0.1; Minimal lumen diameter: 0.85 ± 0.53 mm vs 0.95 ± 0.58 mm, p = 0.3). Acute gain was also similar between the two groups (1.33 ± 0.69 mm vs 1.26 ± 0.68 mm, p = 0.5). At the 6-month angiographic follow-up (follow-up rate: 94%), the incidence of recurrent restenosis (29.2% vs 59.7%, p = 0.0003) and target lesion revascularization (23.6% vs 40.3%, p = 0.036) was significantly lower in the PEB group than in the BA group. Late lumen loss was significantly lower in the PEB group than in the BA group (0.46 ± 0.63 mm vs 0.82 ± 0.73 mm, p = 0.0017).

Conclusions: In patients with recurrent restenosis after DES implantation for in-stent restenosis (stent in stent lesions), PEB provided much better clinical, angiographic outcomes than conventional BA.

TCT-591

Biological Efficacy and Vessel Healing of Second Generation Paclitaxel Coated Balloons: A Comparative Study with the original PACCOCATH Technology in the Ilio-Femoral In-Stent Restenosis Model in the Familial Hypercholesterolemic Swine

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Background: In comparison to the original PACCOCATH formulation, second generation PCB have improved coating uniformity and decreased drug content variability by modifying coating Methods and processes. In this study, we intended to evaluate the differences in biological efficacy and vascular healing response of 2nd generation PCB in comparison to a 1st generation balloons technologies containing identical coating formulation and drug concentration.

Methods: A total of 18 Ilio-femoral arterial segments of 8 FHS were included in the study. At baseline overstretch balloon injury followed by self-expanding BMS implantation was performed. Two weeks following initial injury, all stents were randomized to either a 2nd gen. PCB (n=6, Cotavance V2, Medrad), 1st gen. PCB (n=6, PACCOCATH, Medrad) or POBA (n=6, control group). Imaging evaluation (QVA, IVUS) was conducted in all animals at baseline, treatment time (2 weeks) and 28 days following treatment. At termination, stented segments were harvested for histopathological evaluation.

Results: At last follow up angiographic %DS was significantly reduced in both generations of PCBs when compared to controls (2nd Gen PCB: 11.5 ± 11.1% vs. 1st Gen PCB: 21.9 ± 11.0% vs. POBA: 46.5 ± 10.9%; p<0.01). These findings were confirmed by histopathological analysis (see table) displaying an ~35% reduction of %AS and neointimal thickness in both PCB groups. Vessel healing defined as fibrin deposition, neointimal maturity and medial cell loss scores was significantly improved in 2nd Gen PCB when compared to 1st Gen PCB. Endothelialization was completed in all three groups.